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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,107	10/14/1999	PETER KUFER	3816-4000	6846

7590 07/24/2006
Steven L. Highlander
FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, TX 78701

EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,107

Applicant(s)

KUFER ET AL.

Examiner

David J. Blanchard

Art Unit

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2005 and 13 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18, 19, 31, 32, 38, 39, 55, 56 and 65-67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19, 31, 32, 38, 39, 55, 56 and 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/14/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-17, 20-30, 33-37, 40-54, 57-64 and 68 are cancelled.
Claims 18, 31-32, 65 and 67 have been amended.
2. Claims 18-19, 31-32, 38-39, 55-56 and 65-67 are pending and under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. This Office Action contains New Grounds of Rejections.

Information Disclosure Statement

5. The information disclosure statement submitted on 14 November 2005 has been fully considered by the examiner. A signed copy of the IDS is included with this Office Action. It is noted that Reference C12 listed on the IDS is a duplicate citation, previously cited on the IDS filed 6/30/05 (ref. C22) and has been fully considered. Thus, the duplicate citation has been lined through on the IDS field 11/14/05.

Response to Arguments

6. The objection to the specification as containing sequence disclosures that are encompassed by the sequence rules (37 C.F.R. 1.821-1.825) and require sequence identifiers in Figure 9 is maintained.

The response filed 12/27/2005 has amended the Brief Description of the Figures in the specification for Figs 6-8 with the respective sequence identifiers, however,

applicant has not provided a similar amendment for Figure 9, which still contains sequences that are embraced by the sequence rules and requires sequence identifiers.

"It should be noted, though, that when a sequence is presented in a drawing, regardless of the format or the manner of presentation of that sequence in the drawing, the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings. See MPEP 2422.02.

Appropriate correction is required.

Withdrawn Objections/Rejections

7. All other objections and rejections in the previous Office Action, mailed 21 September 2005 are withdrawn in view of the amendments filed 12/27/2005 and 3/13/2006.

New Grounds of Objections/Rejections

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 18-19, 31-32, 38-39, 55-56 and 65-67 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims,

as written, do not particularly point out any non-naturally occurring differences between the claimed human antibody heavy and light chains and the structure of naturally occurring human antibody heavy and light chains as they exist in human B-lymphocytes/B cells. The claimed DNA encoding the human heavy and light chain immunoglobulin molecules reads upon human heavy and light chains as they naturally occur in human B-lymphocytes/B cells.

In the absence of the hand of man, the naturally occurring antibodies are considered non-statutory subject matter (Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980)). It should be noted that the mere purity of a naturally occurring product does not necessarily impart patentability (Ex parte Siddiqui, 156 U.S.P.Q. 426 (1996)). However, when purification results in a new utility, patentability is considered (Merck Co. v. Chase Chemical Co., 273 F. Supp 68 (1967), 155 U.S.P.Q. 139, (District Court, New Jersey, 1967)). Amendment of the claims to recite "An isolated" or "purified" antibody or antibody fragment would overcome this rejection.

10. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 39 recites the limitation "an antibody or antibody fragment according to claim 19". There is insufficient antecedent basis for this limitation in the claim. Base claim 19 recites that the antibody is an antibody fragment. Thus, there is insufficient antecedent basis for the limitation "an antibody" as presently recited in claim 39.

11. Claims 18-19, 31, 38-39, 55 and 65-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 12/27/2005 has introduced NEW MATTER into the claims. As presently amended base claim 18 recites that the antibody or antibody fragment that binds the human 17-1A antigen comprises a human VH and human VL wherein the VH sequence is from unprimed mature human B-lymphocytes and comprises three CDRs encoded by nucleotides 91 to 105, 148 to 198 and 292 to 351 within nucleotides 1 to 381 of SEQ ID NO:143 and said VL sequence is from a naturally occurring human B cell repertoire and comprises three CDRs encoded by nucleotides 70 to 102, 148 to 168 and 265 to 294 within nucleotides 1 to 321 of SEQ ID NO:141. The response did not point out where support for presently amended claim 18 could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). As presently amended, the claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. For example, there is

insufficient written support for human VH and VL chains that comprise the recited CDR sequences from human VH and VL chains in the context of non-human frameworks or frameworks other than those found in unprimed mature human B-lymphocytes and naturally occurring human B cell repertoires (i.e., human frameworks). The written description of the as filed disclosure is limited to the recited human VH and VL CDR sequences in the context of human frameworks, i.e., nucleotides 1-381 of SEQ ID NO:143 and nucleotides 1-321 of SEQ ID NO:141, obtained from human B-lymphocytes/B cell repertoires screen against the human 17-1A antigen. Thus, there is insufficient written support for the broader limitations of human VH and VL chains obtained from human B-lymphocytes/B cell repertoires that only comprise the recited human CDRs of SEQ ID Nos:143 and 141, respectively. Such limitations recited in the presently amended claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited in the presently amended claims in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

Amending claim 18 to incorporate the limitations recited in dependent claim 32, i.e., the human VH and VL sequences, would overcome this rejection and likely place the present claims in condition for allowance pending an updated search.

Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827

